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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/648,088

08/26/2003

Allan D. Morrison

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12/04/2006

DEWITT ROSS & STEVENS S.C.

8000 EXCELSIOR DR

SUITE 401

MADISON, WI 53717-1914

EXAMINER

SIEFKE, SAMUEL P

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 12/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/648,088

Applicant(s)

MORRISON, ALLAN D.

Examiner

Samuel P. Siefke

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 24-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/24/05</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Claims 24-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/11/06. Applicant's election with traverse of Group II in the reply filed on 9/11/06 is acknowledged. The traversal is on the ground(s) that "The Examiner has provided no indication as to how performing the process by hand is materially different from using the claimed storage container to perform the process, in which case the process is arguably carried by hand in any event". The applicant states, "the claims of Group II can be carried out without the storage container as recited in the claims of Group I, i.e., by hand." The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e))." The Examiner maintains that a proper restriction has been made because the process has been shown to be able to be practiced by hand. In addition, the apparatus as claimed, has separate utility such as a waste container.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 8-15, 17-20, 22 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Gambert et al. (USPN 6,416,715).

Gambert discloses a container for collecting and releasing saliva that comprises a compartment (2) for storage of said sample (saliva) and a closure (3, locking cap) for sealing said compartment, wherein said sealed closure incorporates a locking mechanism whereby the sealed closure is manually inoperable after locking (figure 1-8; col. 3, lines 2-11). Once the saliva sample has been collected on the porous unit 1, the porous unit is retracted into the container and the locking cap is placed thereon end 22 to seal the container, which places the sample into a secured and locked position in the container. The porous unit is made of polyurethane, water-catalyzed polyurethane or cellulose and represents a swab because the device collects a saliva sample by a swabbing action. The container 2 is transparent and can contain colorimetric reagents which upon contact with the saliva sample produce a colorimetric reaction (identifier in claim 6) (col. 3, lines 59-67). The colorimetric reagents (identifier) are within the container so that they are in an inaccessible and resistant to external tampering. The porous unit 1 is attached to a supporting means 4 (sliding platform) which moves the

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porous unit outside the container then back in the container after a sample is on the porous unit. The porous unit moves into a collecting position when the locking cap is removed from the container. The Examiner is interpreting the device to include a memory to record the number of times the sample has been accessed in that the locking tab 34 constitutes at least one use when the tab is broken (see claim 10 of the instant application, physical tab that is broken). Regarding claim 14, the Examiner is interpreting when the locking cap is off the container the sample testing is performed. Regarding claim 15, when the locking cap is on the container (figure 5) the platform moves out (partially withdrawn from container) through an aperture in the locking cap and dispenses the saliva sample.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gambert et al. (USPN 6,416,715) in view of Day (USPN 6,884,397).

Gambert teaches a sample collection container as seen above.

Gambert does not teach a identifier that includes an identification label carrying a barcode.

Day teaches sample tubes with fluid tight labels for providing identifiers for the samples within the sample tubes with includes labels as barcodes. It would have been obvious to one having an ordinary skill in the art at the time of the invention to modify Gambert to employ a barcode label within the transparent container to identify what sample is within the container or what sample analysis is to be performed on the sample. This sample identification is well known in the art and provides simple tracking and organization of samples in mass quantities.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gambert et al. (USPN 6,416,715) in view of Faulkner et al. (USPN 5,624,554).

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Gambert teaches a sample collection container as seen above.

Gambert does not teach a key which unlocks the container.

Faulkner teaches a collection and transfer device that comprises a locking cap with a key 38 which once the cap is on the container, the container is locked until a user employs the key and unlocks the cap. It would have been obvious to one having an ordinary skill in the art at the time of the invention to modify Gambert to employ a key to lock and unlock the locking cap because it provides an extra measure of security for when the container contains a hazardous sample or when the sample is transported and must be ensured that the cap does not come off.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P. Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sam P. Siefke



November 24, 2006



Jill Warden
Supervisory Patent Examiner
Technology Center 1700